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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,307	02/13/2002	Hartmut Strobel	04734.0004	4483

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Washington, DC 20005-3315

EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/073,307

Applicant(s)
Strobel et al.

Examiner
Deepak Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 22, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 ☒ are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-48 ☒ are allowed.
- 6) ☒ Claim(s) 1-4 and 6-20 ☒ are rejected.
- 7) ☒ Claim(s) 5 and 21-23 ☒ are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8 6) ☐ Other:

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DETAILED ACTION

This office action is in response to the amendment filed on September 22, 2003.

Claims 1-48 are pending in this application.

The following rejections are withdrawn:

The rejections under 35 U.S.C. 112, second paragraph of the previous office action are withdrawn in view of the amendments and remarks.

The rejection under 35 U.S.C. 102(b) over Niewoehner (EP'257) is hereby withdrawn in view of the amendments and/or applicant's remarks.

The rejection under 35 U.S.C. 103(a) over Albrecht et al. (CA 77:88182) of the previous office action is withdrawn in view of the amendments.

The following rejections are maintained:

1. Claims 1-4, 6-9, 11-15 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Beasley et al., WO 97/04775, for the reasons provided in the previous office action which are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that the reference disclosed compounds do not contain the group corresponding to R⁵ of the instant claims. However, the instant claims define R⁵ to be Hetero which can be further condensed to a '5- to 7-membered heterocycle containing 1-3 heteroatoms

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chosen from N, O and S, which heterocycles can be substituted by oxo, etc.’ Therefore, the reference disclosed 8-ethyl-5,8-dihydro-5-oxo-2-(1-pyrrolidiny1)-pyrido[2,3-d]pyrimidine group does fall within the definition of R⁵ of instant claims. Therefore, the rejection is maintained.

2. Claims 6-9, 11-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Horn et al., EP 420064, for the reasons provided in the previous office action which are incorporated here by reference.

Applicant’s arguments have been fully considered but they were not deemed to be persuasive. Applicant submits that the reference does not teach “stroke” as indicated in the office action and further, argues that the reference highlights melatonin activity of the compounds. However, the reference clearly teaches the compounds to be useful in therapeutic applications, including for sexual dysfunction (see page 5, line 18) which are identical to those intended by the instant claims. Thus, the reference teaches the administration of the same compounds to the same patient population. Applicant argues that the reference does not provide that the compounds could act on NO-synthase. This is not found to be persuasive because as explained above the reference teaches therapeutic use of the compounds for treatment of diseases including sexual dysfunction. The reference discloses the compounds recited in the instant claims, teaches their therapeutic activities and the corresponding effects, including the treatment of the diseases recited in the instant claims (e.g., erectile dysfunction) and therefore, it is submitted that the instant claims do not recite “new use” of the compounds. The mode of action

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of NO-synthase is a property inherently possessed by the compounds of the reference. This biological property is inherently possessed by the reference compounds particularly because the compounds are used in the same therapeutic applications as recited in the instant claims. The properties possessed by the compounds, whether explicitly or inherently, can not be separated from the compounds itself.

Applicant cited several Board and Federal Circuit decisions and argued that ‘no basis or technical reasoning has been provided to support the inherency rejection’. Applicant’s attention is directed to *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978), wherein it was stated that “applicants merely found a new property of the compound and such a discovery did not constitute a new use”, which appears to be particularly relevant to the instant fact situation.

For all the above reasons, the rejection under 35 U.S.C. 102(b) is maintained.

The following rejections are under new grounds:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al., WO 00/51970. The reference discloses amide compounds (see formula (I) in page 2 and the species of Example 8) and the reference discloses that the compounds have therapeutic effect on various diseases, including stroke, etc. (see page 1, lines 18+). The instant claims read on the prior art taught therapeutic effect because the instant claims are drawn to administration of the

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prior art compounds, in same dosages, to the same population. The therapeutic effect of claims 6-10 is evident from the dependent claims 12-16. The prior art also teaches that the compounds are useful in the treatment of the instantly claimed disease of stroke, etc. and therefore, the instantly claimed mechanism of stimulating the expression of endothelial NO-synthase is inherently taught in the reference.

Allowable Subject Matter

Claims 24-48 are allowed. The references do not teach or fairly suggest the instantly claimed methods.

Claims 5 and 21-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The references of record do not teach or fairly suggest the instantly claimed compounds and/or methods.

Receipt is acknowledged of the Information Disclosure Statement filed on September 22, 2003 and a copy is enclosed herewith.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Deepak Rao
Primary Examiner
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December 15, 2003